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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,393	01/31/2006	Zi-Hua Jiang	GANDHIIA	6722
1444 7590 02/03/2010 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER PESELEV, ELLI	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 02/03/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/529,393

**Applicant(s)**

JIANG ET AL.

**Examiner**

Ellie Peselev

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2009 and 22 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 10-14, 17-20, 50, 51, 63-65, 92-105, 107-146 and 148-231 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50, 51 and 63-65 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 10, 14, 17-20, 92-105, 107-146, 148-157 and 159-231 is/are rejected.
- 7) ☒ Claim(s) 158 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of Priorities Claimed (PTO-402)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Claims 1-4, 7, 10-14, 17-20, 92-105, 107-146, 148-157 and 159-231 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the claimed invention without undue experimentation.

(a) The breadth of the claims.

The compound claims encompass an enormous number of compounds having structurally unrelated chemical structures. For examples, a compound wherein R is one or more polysaccharides, Ch is nitrogen would not be expected by one of ordinary skill in the art at the time the present invention was made to have similar activity as a compound wherein R is a single monosaccharide and Ch is O.

The method claims 107-139 read on a method of protecting a mammalian subject against a virus, microbial infection, parasite or cancer. The term "protection" encompasses prevention. The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. There is no evidence that entry would be prevented. Further, there is no evidence that the claimed compounds are useful in preventing cancer.

(B) The level of predictability in the art.

It is well known in the art that changes in the structural formula of a compound can lead to significant changes in the activity of said compound. For example, claim 1 reads on a compound wherein R can be any number of carbohydrate moieties. The term "carbohydrate" encompasses monosaccharides, oligosaccharides and polysaccharides. A compound wherein R is a single monosaccharide, would not be expected by a person of ordinary skill in the art to have similar activity to a compound wherein R is one or more polysaccharides such as agarose or guar gum.

(C) The amount of direction provided by the inventor.

The specification provides examples of 14 specific compounds having closely related structural formulas. For example, the structural formulas of the said compounds are limited to compounds wherein R is a monosaccharide and Ch is O. This is clearly not commensurate with the full scope of the claimed invention.

(D) The quantity of experimentation needed to make and/or use the invention.

Because there is no way to predict a priori which compounds encompassed by the present claims will be active from the specification or chemical structure alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Applicant's arguments filed October 7, 2009 and October 22, 2009 have been fully considered but they are not persuasive.

Behar et al (US 2002/0115624) discloses alpha-glycoceramides useful for the treatment of bacterial and fungal infections [0007]. The present claims encompass compounds wherein R is more than one carbohydrate and wherein carbohydrate is a

polysaccharide. Further, the prior art compounds and the specific compounds disclosed in the present specification are limited to compounds wherein Ch is oxygen. There is no evidence in the prior art or the present specification that compounds wherein R is more than one monosaccharide or at least one polysaccharide or wherein Ch is nitrogen has any biological activity.

With respect to method claims, the term "protecting" has not been defined in the specification. Therefore, the claimed methods encompass administering claimed compounds to a healthy mammal and preventing said mammal from ever developing a viral, microbial or parasitic infection or cancer. Glycosyl ceramides are not known to be useful in preventing microbial infections and cancer and no evidence of such prevention has been provided.

Claims 1-4, 7, 10-14, 17-20, 92-105, 107-146, 148-157, 159-231 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure in the specification, as originally filed for the newly amended and the newly presented claims 159-215. For example, there is no disclosure in the specification as originally filed for the terminology "one or more spacers, and optionally a trivalent or tetravalent linker" (claim 1), "R is a carbohydrate moiety consisting of 1-20 sugar units" (claim 161), "R is a carbohydrate moiety consisting of 1-6 sugar units" (claim 162) "R is the carbohydrate moiety of a naturally

occurring glycosphingolipid or glycosceramide, or the carbohydrate epitope of a naturally occurring antigen" (claim 163), "R is the carbohydrate moiety of a naturally occurring glycosceramide" (claim 164), "wherein the inner sugar unit is glucose" (claim 165), (claim 165), "wherein the carbohydrate moiety consists of 1-6 sugars:" (claim 167), "wherein R is the carbohydrate moiety of a naturally occurring glycosceramide" (claim 168), "hydrocarbon" (claim 172 and 183, 201, 205 and 214), "R3 is characterized by 10-49 carbon atoms and R3' is characterized by 2-10 olefinic forms" (claim 173 and 184 and 202 and 206 and 215),

Note that on page 15 of the specification carbohydrate moiety is defined as being preferably a monosaccharide and, with galactose being especially preferable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623